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09/547,501	04/12/2000	Samuel T. Christian	IMI-001	6126

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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

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16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/547,501

Applicant(s)

CHRISTIAN, SAMUEL T.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 22, 2002, March 11, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 6-9, 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,5 and 10-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicant's preliminary amendment in response to the Restriction Requirement in Paper No. 3, submitted March 11, 2002 in Paper No. 9, is acknowledged, wherein claims 41, 4-5, and 10-40 have been amended. Currently, claims 1-42 are pending in this application.

Election/Restrictions

Applicant's election with traverse of the invention of Group IV, claim 41, in Paper No. 4 submitted July 27, 2001, and species election of the dopamine-2-amide-carbohydrate-conjugated compound, a sub-species of formula I in claim 41, submitted July 22, 2002 in Paper No. 13, are acknowledged.

In view of Applicant's preliminary amendment in response to the Restriction Requirement, submitted March 11, 2002 in Paper No. 9, the elected invention of Group IV, is modified to include claims 41, 4-5, and 10-40.

The traversal is on the ground(s) that inventions I-IV are all related to the instant compounds. This is not found persuasive. As discussed in the Requirement for Restriction, Group I; and III-IV are related as product and process of use, the criteria for distinct inventions: (1) the process for using the product as claimed can be practiced with another materially different product (MPEP § 806.05(h)). In the instant case, for example, L-dopa may be used a method for treating a neurological dysfunction. Thus, the composition containing L-dopa is another materially different product -- which is

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materially different from the product as claimed, a carbohydrate conjugated compound, can be used in the claimed method herein for treating a neurological dysfunction.

Moreover, the search field for a composition is non-coextensive with the search field for a method of treating a patient employing the same composition. A reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103.

Inventions Group II; and I, III-IV are unrelated to each other, being a separate and distinct from each other since they have different functions.

Thus, an undue burden on the Office is seen for the search all inventions herein, as discussed in the Requirement for Restriction. Note that the search is not limited to patent files.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

Claims 1-3 and 6-9, 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 41, 4-5, and 10-40 will be examined on the merits herein.

The claims have been examined insofar as they read on the elected specie.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 4-5, 11-20 and 23-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-5 recite the limitation "the pharmaceutical composition" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

The recitations, "the remaining of X or Y comprising a carbon atom" in claim 11, "X and Y comprising a lower alkyl.." in claims 14-15, "Z comprises a lower alkyl.." in claim 16, and "N comprises an amide.." in claims 19-20, render claims 11-20 indefinite. These recitations are not clear to be understood to one of ordinary skill in the art since according to the definitions of X, Y, N, and Z herein, they are all single atoms not a functional group. Hence, a single atom cannot contain or comprise an additional group. Further, one of ordinary skill in the art would not understand what would be "the remaining of X or Y.." in claim 11.

The expression "derivatives thereof" in claims 23-40 renders claims 23-40 indefinite. The expression "derivatives thereof" is not seen to be clearly defined in the specification. Hence, one of ordinary skill in the art could not interpret the metes and bounds as to the recitation "derivatives thereof" in the claim. Therefore, the scope of the claims is indefinite as to what would be considered "derivatives thereof" encompassed thereby.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41, 4-5, and 10-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Likhoshersfov et al. (PTO-892) in view of Mizuma et al. (72 and 73, PTO-1449 submitted November 13, 2000) and Takata et al. (96, PTO-1449 submitted November 13, 2000), and Vannucci et al. (99, PTO-1449 submitted November 13, 2000).

Likhoshersfov et al. discloses the incorporation of carbohydrate residues into active compounds such as dopamine to form dopamine glycoconjugates, the instant elected species (see abstract).

Likhoshersfov et al. does not expressly disclose the employment of the incorporation of carbohydrate residues into active compounds (active drugs) such as dopamine glycoconjugates in a composition and a method for improving the aqueous solubility and blood brain barrier penetrability of a drug.

Mizuma et al. teaches that sugar-conjugated drugs such as glucose-conjugated compounds provide these compounds (drugs) with a new route by the way of the glucose transport carrier for better absorption in intestine, improving the poorly absorbable drugs (see abstract).

Both Takata et al. and Vannucci et al. teach the transport of glucose across the blood-tissue barriers such as blood-brain barrier (see abstracts).

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It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ conjugates of carbohydrate residues and active compounds (active drugs) such as dopamine glycoconjugates in a composition and a method for improving the aqueous solubility and blood brain barrier penetrability of a drug.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ conjugates of carbohydrate residues and active compounds (active drugs) such as dopamine glycoconjugates in a composition and a method for improving the aqueous solubility and blood brain barrier penetrability of a drug, since active compounds (active drugs) such as dopamine glycoconjugates are known according to Likhoshersfov et al. Moreover, the teachings of Mizuma et al., Takata et al. and Vannucci et al. have provided the motivation to make conjugates of carbohydrate residues and active drug compounds herein since sugar-conjugated drugs such as glucose-conjugated compounds provide these compounds (drugs) with a new route by the way of the glucose transport carrier for better absorption in intestine and improving the poorly absorbable drugs, and also enhancing the blood brain barrier penetrability of a drug.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
June 23, 2003